

In the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1-26 (canceled)

27. (original) Leflunomide prepared by a process comprising the steps of:

- a) providing 5-methylisoxazole-4-carboxylic acid chloride and
- b) contacting the 5-methylisoxazole-4-carboxylic acid chloride with 4-trifluoromethylaniline in the presence of an alkali metal or alkaline-earth metal bicarbonate in an acylation solvent system comprising at least one solvent component selected from the group consisting of water, ethyl acetate, toluene and dimethyl acetamide, and
- c) isolating the leflunomide.

28. (original) The leflunomide of claim 27 wherein 5-methylisoxazole-4-carboxylic acid chloride is provided as crude 5-methylisoxazole-4-carboxylic acid or a residue by:

- a) chlorinating 5-methylisoxazole-4-carboxylic acid by contacting it with a chlorinating agent to form crude 5-methylisoxazole-4-carboxylic acid chloride and
- b) optionally evaporating excess chlorinating agent or volatile byproducts of the chlorination under reduced pressure, whereby the evaporation leaves a residue of unevaporated material containing 5-methylisoxazole-4-carboxylic acid chloride.

29. (original) The leflunomide of claim 27 which is substantially free of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

30. (original) The leflunomide of claim 29 containing about 150 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

31. (original) The leflunomide of claim 30 containing about 100 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

32. (original) The leflunomide of claim 31 containing about 50 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

33. (original) The leflunomide of claim 32 containing about 10 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
34. (original) The leflunomide of claim 27 which is substantially free of 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide.
35. (original) The leflunomide of claim 27 which is substantially free of N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.
36. (original) The leflunomide of claim 27 substantially free of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide, 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide and N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.
37. (original) A pharmaceutical composition comprising the leflunomide of any of claims 27 through 36.
38. (original) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 37.
39. (original) A method of treating rheumatoid arthritis comprising administering to a patient in need of such treatment a therapeutically effective amount of the leflunomide of any of claims 27 through 36.
40. (original) A method of regulating cell proliferation comprising administering to a patient an amount of the leflunomide of any of claims 27 through 36 sufficient to inhibit cell proliferation.